



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee;

Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 21, 2014, from 8 a.m. to 3 p.m.

Location: Hilton Washington DC North/Gaithersburg, Salons A, B, C and D, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900.

Contact Person: Sara Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1643, Silver Spring, MD 20993-0002, [Sara.Anderson@fda.hhs.gov](mailto:Sara.Anderson@fda.hhs.gov), 301-796-7047, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On February 21, 2014, the committee will discuss and make recommendations regarding the 515(i) order issued by FDA on April 9, 2009 [Docket No. FDA-2009-M-0101], relating to the regulatory classification of iontophoresis devices, one of the remaining preamendments class III devices. Iontophoresis is a method of non-invasive transdermal delivery in which a substance bearing a charge is propelled through the skin by an electric current. Iontophoresis devices generally consist of a controller, active and return electrode(s), and power supply used to deliver currents to transport drugs, soluble salts, or ionic solutions across the skin.

The regulation for iontophoresis devices (21 CFR 890.5525) currently has two parts. Part (a) of the regulation classifies iontophoresis devices as class II when indicated to introduce drugs or soluble salts to induce sweating for use in the diagnosis of cystic fibrosis or for other uses if the drug intended for use with the device bears adequate directions for the device's use with that drug. Devices identified in part (a) of the regulation will not be considered in the scope of the committee meeting. Part (b) of the regulation classifies iontophoresis devices as class III when intended to use direct current to introduce soluble salts or other drugs into the body for purposes other than those specified in part (a). Devices identified in part (b) of the regulation are the subject of the committee meeting.

On August 28, 1979, FDA published a proposed rule (44 FR 50520) for classification of iontophoresis devices for specialized uses (for the diagnosis of cystic fibrosis, fluoride uptake

acceleration in dentistry, and for local anesthesia of the intact tympanic membrane) into class II and for all other uses into class III. FDA recommended class III for iontophoresis devices when used for purposes other than those specifically considered because such use presents "a potential unreasonable risk of injury without benefit to the patient because substantial data and clinical investigations do not exist to support the claims made for the devices." In addition, the Agency noted that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard to provide this assurance.

Subsequent to the proposed rule, FDA published a final rule (48 FR 53047) on November 23, 1983, classifying iontophoresis devices for use in the diagnosis of cystic fibrosis or other uses if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug as class II (performance standards) and iontophoresis devices intended for any other purposes as class III (premarket approval). The final rule was issued after consideration of three comments submitted in response to the 1979 proposed rule that disagreed with the proposal classifying into class III iontophoresis devices for uses other than diagnosing cystic fibrosis, application of fluoride in dentistry, or anesthetizing the tympanic membrane. Based on FDA's analysis of the available literature and input from the Physical Medicine; Ear, Nose and Throat; and Dental Device Classification Panels (see the preamble to the proposed rule 44 FR 50520), FDA disagreed with the comments and concluded that insufficient data exist to support uses of the device other than those specifically considered. In addition, the final rule removed the dental application of fluoride and local anesthesia of the intact tympanic membrane uses from the class II definition because it was determined that there were no marketed drugs

with adequate instructions for use with an iontophoresis device for these uses. The effect of this change in the identification was to classify into class III iontophoresis devices for these two uses.

In 1987, FDA published a clarification by inserting language in the codified language stating that no effective date had been established for the requirement for premarket approval for iontophoresis devices intended for any other purposes (52 FR 17742, May 11, 1987).

On August 22, 2000, FDA published a proposed rule (65 FR 50949) to amend the iontophoresis device regulation to remove the class III (premarket approval) identification because FDA believed there were no preamendments iontophoresis devices marketed for uses other than those described in the class II identification. The proposed rule stated that manufacturers of iontophoresis devices that had been cleared as class III 510(k)s could revise the labeling of their devices to meet the class II identification.

On November 4, 2004, FDA withdrew the proposed rule issued on August 22, 2000 (65 FR 50949), in response to comments received (69 FR 64266). FDA simultaneously issued a Notice of Intent to reclassify iontophoresis devices currently in class III into class II (special controls) and provided an opportunity for interested persons to submit any new information concerning the safety and effectiveness of iontophoresis devices (69 FR 64313). FDA did not take further regulatory action regarding iontophoresis devices prior to issuing the 2009 515(i) order on April 9, 2009 [Docket No. FDA-2009-M-0101], relating to their regulatory classification.

The discussion at the committee meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to PMA), or reclassify to class I or class II (subject to 510(k)). The committee will further be asked to comment on whether general and/or special controls are adequate to reasonably ensure the safety and

effectiveness of the device and whether, if reclassified to Class II, these devices should be exempt from premarket notification requirements.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before January 31, 2014. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m. on February 21, 2014. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 23, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 24, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams at [Annmarie.Williams@fda.hhs.gov](mailto:Annmarie.Williams@fda.hhs.gov), 301-796-5966, at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 17, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.